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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/577,414

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Nigel Cronin

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EXAMINER

HUPCZEY, JR, RONALD JAMES

ART UNIT

PAPER NUMBER

3739

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/577,414	Applicant(s) CRONIN ET AL.	
	Examiner RONALD J. HUPCZEY, JR.	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 April 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/12/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. The priority date for the instant application is July 2nd, 2004.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: the reference sign "106" found on page 6, line 30 in regard to figure 5 is missing from the figure.
3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: the reference character "704" in figure 7.
4. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 13, the recitation therein is unclear and confusing. The holes are disclosed as a being at a predetermined distance, but the claim fails to set forth a structural relationship between the holes and another portion of the applicator in order for one to determine their location on the applicator. Appropriate correction is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Prakash et al (US Pub. No. 2003/0088242 A1).

Regarding claim 1, Prakash et al discloses a radiation applicator containing an axial inner conductor (inner conductor **44**) adapted to be coupled to a source of electromagnetic radiation and defining an axis, an elongate dielectric member (dielectric material **46**) surrounding at least part of the central conductor along an axial length and a metal ferrule (junction member **40, 62, 86**, see paragraph [0060], figure 6) attached to the dielectric member and surrounding a portion of the central conductor and extending parallel along a length of the central conductor.

Regarding claim 2, Prakash et al discloses the ferrule and the dielectric member to have respective elongate cooperative surfaces (see figure 6, interface between junction member **104**

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and dielectric **114**) and for the ferrule and the dielectric member to be fixedly attached to one another via the abutment of those cooperating surfaces wherein the joining results in a rigid structure (see paragraph [0063]).

Regarding claim 3, Prakash et al discloses the cooperating surfaces to include radially extending cooperating surfaces (see figure 6, stepped interface points between junction member **104** and dielectric **114**).

Regarding claim 4, Prakash et al disclose the cooperating surfaces to include respective annular cooperative surfaces (steps of junction member **104**).

Regarding claim 5, Prakash et al discloses the applicator to further contain a disc shaped tuning conductor (distal portion **48**) attached to the central conductor and in electrical contact such that the shape and dimensions of the tuning conductor and the dielectric member determined to form a radiating dipole extending radially from the dielectric member (see paragraphs [0057] and [0060]).

Regarding claim 15, Prakash et al discloses the external diameter of the dielectric member, the ferrule, and/or metal tube to be less than 2.5mm (see paragraph [0058]).

9. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Carl et al (US Pat. No. 6,047,216).

Regarding claim 1, Carl et al discloses a radiation applicator containing an axial inner conductor (conductor **314**) adapted to be coupled to a source of electromagnetic radiation and defining an axis, an elongate dielectric member (core **316**) surrounding at least part of the central conductor along an axial length and a metal ferrule (metal choke **318**, see figure 3) attached to the

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dielectric member and surrounding a portion of the central conductor and extending parallel along a length of the central conductor.

Regarding claim 2, Carl et al discloses the ferrule and the dielectric member to have respective elongate cooperative surfaces (see figure 3, interface between metal choke **318** and core **316**) and for the ferrule and the dielectric member to be fixedly attached to one another via the abutment of those cooperating surfaces wherein the joining results in a rigid structure.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carl et al (US Pat. No. 6,047,216) as applied to claim 2 above, and further in view of Turovskiy et al (US Pat. No. 7,311,703 B2).

Regarding claims 6 and 16, Carl et al discloses the central conductor to contain the inner conductor (conductor **314**) of a cable. Carl et al fails to specifically recite a metal tube surrounding the central conductor, the ferrule to be attached to the dielectric member and the metal tube and for the metal tube and cable to define an annular space therebetween which permits the passage of cooling fluid. Turovskiy et al discloses a similar microwave antenna assembly which supplies cooling to the radiating portion of the antenna. Turovskiy et al further discloses a metal tube (outer jacket **108**) surrounding a portion of the central conductor (antenna **104**, radiating portion **106**) and for the metal tube and central conductor to define an annular space (fluid channel **134**) which permits passage to the radiating section of the antenna. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a metal tube such as that of Turovskiy et al in combination with the disclosed structure of the antenna of Carl et al to provide for an applicator which is also cooled. In construction, to provide for a rigid structure capable of being maneuvered to a target portion of tissue, it would advantageous to rigidly secure the metal tube of Turovskiy et al to the dielectric member via the ferrule of Carl et al. Additionally, the provision of cooling of a microwave antenna is well known in the art and ensures that the target tissue which is connected is not unnecessarily ablated or charred due to heating of the applicator structure.

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Regarding claim 16, Carl et al discloses a radiation applicator containing an axial inner conductor (conductor **314**) adapted to be coupled to a source of electromagnetic radiation and defining an axis, an elongate dielectric member (core **316**) surrounding at least part of the central conductor along an axial length and a metal ferule (metal choke **318**, see figure 3) attached to the dielectric member and surrounding a portion of the central conductor and extending parallel along a length of the central conductor. Carl et al further discloses the central conductor to contain the inner conductor (conductor **314**) of a cable. Carl et al fails to specifically recite a metal tube surrounding the central conductor, the ferrule to be attached to the dielectric member and the metal tube and for the metal tube and cable to define an annular space therebetween which permits the passage of cooling fluid. Turovskiy et al discloses a similar microwave antenna assembly which supplies cooling to the radiating portion of the antenna. Turovskiy et al further discloses a metal tube (outer jacket **108**) surrounding a portion of the central conductor (antenna **104**, radiating portion **106**) and for the metal tube and central conductor to define an annular space (fluid channel **134**) which permits passage to the radiating section of the antenna. Additionally, Turovskiy et al discloses a fluid conduit (distal end **132** of fluid inlet **126**) connected to a source of cooling fluid via a pump (see col. 8; 35-38) wherein the pump provides fluid at a predetermined rate to the annular space (see col. 9; 16-29). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a metal tube and supporting cooling structures as that of Turovskiy et al in combination with the disclosed structure of the antenna of Carl et al to provide for an applicator which is cooled. In construction, to provide for a rigid structure capable of being maneuvered to a target portion of tissue, it would advantageous to rigidly secure the metal tube of Turovskiy et al to the dielectric

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member via the ferrule of Carl et al. Additionally, the provision of cooling of a microwave antenna is well known in the art and ensures that the target tissue which is connected is not unnecessarily ablated or charred due to heating of the applicator structure.

14. Claim 14 rejected under 35 U.S.C. 103(a) as being unpatentable over Carl et al (US Pat. No. 7,311,703 B2) as applied to claim 2 above, and further in view of Prakash et al (US Pub. No. 2003/0088242 A1).

Regarding claim 14, Carl et al fails to disclose the dielectric member to be formed into a blade wherein the blade has a dimension of elongation transverse to the axis. Prakash et al discloses a similar radiation applicator in which the tip of the device is tapered to a form a sharpened tip (see figure 5, paragraph [0065]). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a blade such as that of Prakash et al with the applicator of Carl et al to allow for an applicator which is easily advanced into a target portion of tissue. Furthermore, the provision of a sharpened tip (blade) on an applicator is a well known and commonly utilized structure to facilitate the insertion of an applicator into tissue.

15. Claims 7-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carl et al (US Pat. No. 6,047,216) and Turovskiy et al (US Pat. No. 7,311,703 B2) as applied to claim 6 above, and further in view of Ni et al (US Pat. No. 6,514,251 B1).

Regarding claims 7, 8, 10 and 11, Carl et al and Turovskiy et al fail to disclose holes provided in the metal tube to provide for fluid conduits between the annular space and the exterior of the application. Ni et al discloses an applicator which utilizes a cooling system which provides for radially extending holes (see figures 3, 4 and 6, openings **35, 41**) placed in the outer

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tube of the applicator to provide fluid outflow from the annular space to the outside of the applicator. Ni et al further discloses the holes to be diametrically opposed and for the holes to be spaced apart axially (see placement of holes in figures 3, 4 and 6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide at least one set of holes in the metal tube of the combined device of Carl et al and Turovskiy et al as displayed by Ni et al to provide for an electrode which cools both the applicator assembly itself and the tissue which is contacted by the applicator in order to prevent unwanted charring and overheating of the target tissue.

Regarding claim 9, Carl et al, Turovskiy et al and Ni et al fail to specifically recite the number of holes found per set. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide 1 to 4 holes per set in order to provide sufficient fluid outflow to the target tissue. While applicant's specification does recite the criticality of ensuring effective fluid flow, it should be noted that Ni et al also provides for such a criticality (see col. 4; 1-27) and that the fluid flow rate into the applicator as well as the number of holes would be an obvious variation to the applicator which would directly effect the fluid flow to the exterior of the applicator.

Regarding claim 12, Carl et al, Turovskiy et al and Ni et al fail to specifically recite the diameter of holes. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a diameter of 0.1 to 0.6mm per hole in order to provide sufficient fluid outflow to the target tissue and to maintain the structural integrity of the applicator. While applicant's specification does recite the criticality of ensuring effective fluid flow, it should be noted that Ni et al also provides for such a criticality (see col. 4; 1-27) and that

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the fluid flow rate into the applicator as well as the number of holes and the diameter of each hole would be an obvious variation to the applicator which would directly effect the fluid flow to the exterior of the applicator.

Regarding claim 13, Carl et al, Turovskiy et al and Ni et al fail to specifically recite the location of the holes on the applicator. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a location of anywhere from 3 to 50mm of placement in order to provide for adequate cooling to the portion of target tissue the applicator is inserted into. While applicant's specification does recite the criticality of ensuring effective fluid flow to the portion of tissue to be treated, it should be noted that Ni et al also provides for such a criticality (see col. 4; 1-27) and that the fluid flow rate into the applicator as well as the location of the holes would be modified as such to ensure that effective cooling is applied to the complete portion of target tissue treated.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Vitullo et al (US Pub. No. 2005/0245920 A1), Carr (US Pat. No. 6,496,738 B2), Campbell et al (US Pat. No. 5,800,494) and Arndt et al (US Pat. No. 5,904,709).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD J. HUPECZEY, JR. whose telephone number is (571)270-5534. The examiner can normally be reached on Mon. - Fri. from 8am to 5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. J. H./
Examiner, Art Unit 3739

/Michael Peffley/
Primary Examiner, Art Unit 3739

RJH